

### **REMARKS**

Upon entry of this amendment, claims 1, and 3-26 will be pending in this patent application. Claims 9-10, and 18-26 are withdrawn as directed to non-elected subject matter. Claims 1-8 and 11-17 were examined and stand rejected as follows: Claim 1 is objected to for informalities. Claims 2-4, 8, and 17 stand rejected under 35 U.S.C. §112, first paragraph as allegedly not enabled by the specification. Claims 1, 5-7, and 11-14 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Pat. No. 4,800,903. Claim 16 stands rejected under 35 U.S.C. §103(a) as allegedly an obvious variant of the '903 patent. Claim 15 stands rejected under 35 U.S.C. §103(a) as allegedly obvious over the '903 patent in view of U.S. Pat. No. 2,818,868. Claims 2-4 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over the '903 patent in view of the Calleson memo. Claims 2, 8, and 17 are canceled herein, without prejudice. Claims 1 and 13 are amended herein, without the addition of new matter.

It is believed that the amendments to claim 1 adequately address the objection, and reconsideration is requested on this bases.

With respect to the issue of enablement of claims 2-4, Applicants disagree that the claims are not enabled. The Applicants discovered that the problem with prior art containers for smokeless nicotine inhalation was that users were unable to receive sufficient nicotine per puff to experience satisfaction, and that this problem was a function of high flow resistance in the nicotine container. The Applicants further discovered that the problem of high flow resistance could be overcome by preparing a container having a particular length and diameter, and nicotine-saturated filaments at particular densities in order to obtain the optimized flow resistance. Optimized flow resistance increases the volume of air inhaled per puff, thereby increasing the amount of nicotine being inhaled per puff. The optimized flow resistance is reflected in the claims.

The enablement requirement is fulfilled if any mode of making and using the invention is described. *Engel Industr. v. Lochformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991) (“[t]he enablement requirement is met if the description enables **any** mode of making and using the invention”)(emphasis added); see also *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005) (“Enablement does not require the inventor to foresee

every means of implementing an invention at pains of losing his patent franchise. Were it otherwise, claimed inventions would not include improved modes of practicing those inventions. Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain.”). The test for enablement is not whether experimentation is required, but whether, if experimentation is required, such is undue. *In re Angstadt*, 537 F.2d 498, 504 (CCPA 1976).

It is submitted that preparation of a container that provides the flow resistance requirements recited in the claims is well within the capabilities of those of ordinary skill in the art, and that nothing more than routine experimentation is required to achieve the optimized flow resistance recited in the claims. The particular method used to measure flow resistance is not critical and can vary with the needs of the particular investigator, and numerous means are available in the art to measuring flow resistance and would be expected to be known to those of skill in the art. For example, standard methods for measuring pressure drop are available from the American National Standards Institute (ANSI) and from ASTM International. ASTM and ANSI administer voluntary standardization and conformity assessment systems throughout the United States and the world. Thus, any experimentation undertaken to determine whether a container as recited in the claims also provides the claimed flow resistance would not be undue. The claims are thus enabled, and reconsideration of the rejection is requested.

### **Rejection under 35 U.S.C. §102**

The office action states that the ‘903 patent discloses a shaped mass of polyethylene filaments that absorbs nicotine and a film to wrap the filaments. To the extent the rejection would be maintained against the amended claims, Applicants disagree. The ‘903 patent does not teach or suggest the claimed flow resistance and does not teach or suggest encapsulation with a nicotine impermeable polymer. Indeed, the ‘903 patent fails to even recognize the problem of inadequate nicotine delivery that is caused by too high a flow resistance. As not all of the limitations of the claimed invention are not taught or suggested by the cited art, the claims are not anticipated by the ‘903 patent.

Moreover, since the '903 patent fails to recognize the problem addressed by the present invention, much less the solution provided by Applicants' invention, the reference also does not render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the rejection over the '903 patent be withdrawn.

### **Rejections under 35 U.S.C. §103**

With respect to claim 16, the office action states that the '903 patent provides the inventive container, but does not disclose production of fibers or filaments by spinning or extrusion. It is alleged that it is well known to make fibers by spinning, and thus it would be an obvious modification of the '903 teachings to make the present invention by spinning or extrusion. Applicants disagree with the rejection. As set forth above, the '903 patent does not teach or suggest all of the limitations of the claimed invention. Accordingly, producing the inventive containers by spinning or extrusion is not an obvious modification of the '903 patent to arrive at the claimed invention.

With respect to claim 15, the office action alleges that although the '903 patent does not disclose the use of PET as a fiber or filament, such a use would be obvious because the '868 patent uses PET as a fiber in cigarette filters. To the extent the rejection would be maintained against the amended claims, Applicants disagree. First, as set forth above, the '903 patent does not teach or suggest all of the limitations of the independent claim from which claim 15 depends. The '868 patent does not remedy the deficiencies of the '903 patent because the '868 patent does not teach or suggest the claimed flow resistance or encapsulation. In addition, the present invention is not directed to cigarettes and does not use PET as a filter. Those of skill in the art would not consider a reference teaching of the use of PET as a cigarette filter (*i.e.*, in a device for smoking) when considering materials to releasably retain nicotine in a smoking cessation device. Thus, a *prima facie* case for obviousness has not been established.

With respect to claims 2-4, the office action states that although the '903 patent does not provide the claimed flow rates, such would be obvious because the Calleson memorandum recites some factors that control pressure drop over a cigarette. To the extent the rejection would be maintained against the amended claims, Applicants disagree. First, as

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set forth above, the '903 patent does not teach or suggest all of the limitations of the independent claim from which claims 3 and 4 depend. The Calleson memorandum does not remedy the deficiencies of the '903 patent because it does not teach or suggest the claimed flow resistance or encapsulation. In addition, the Calleson memorandum describes the factors that affect cigarette tar yield. The reference does not teach or suggest that optimized flow resistance is a factor to consider to achieve the proper amount of nicotine released from inhaling a tobacco-less smoking cessation container, and moreover does not teach or suggest the claimed flow resistance values or how to achieve the claimed flow resistance values. Thus, the cited references, alone or in combination do not provide all of the limitations of the claimed invention. *A prima facie* case for obviousness has not been established.

Applicants request entry of this amendment. Applicants respectfully submit that in light of the amendments and remarks made herein, the claims are in condition for allowance. Favorable reconsideration of the various rejections and a notice of allowance are earnestly requested.

Respectfully Submitted,

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